



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/241,455	02/02/1999	NIKOLAI M. KRIVITSKI		8764

23387 7590 01/08/2003

Stephen B. Salai, Esq.
Harter, Secrest & Emery LLP
1600 Bausch & Lomb Place
Rochester, NY 14604-2711

EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT PAPER NUMBER

3736

DATE MAILED: 01/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/241,455

Applicant(s)

KRIVITSKI, NIKOLAI M.

Examiner

Brian Szmaj

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6,9-19 and 22-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6,9-19 and 22-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 43 is rejected under 35 U.S.C. 102(e) as being anticipated by Quinn et al ('654).

Quinn et al disclose a multi-lumen, multi-parameter catheter and further disclose the use of a catheter body having a balloon; a port in the catheter body for inducing a blood property change to flowing blood external to the catheter; and a sensor affixed to the catheter and spaced away from the blood property change port to provide a signal corresponding to a change in blood property external to the catheter. See Column 3, lines 25-63; Column 4, lines 60-67; Column 5, lines 1-7 and 26-49; and Column 6, lines 35-44.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-6, 9-19 and 22-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn et al ('654) in view of Vogel et al ('110).

Quinn et al, as discussed above, disclose a multi-lumen, multi-parameter catheter and further disclose the use of a catheter body having a balloon; a port in the catheter body for inducing a blood property change to flowing blood external to the catheter; a sensor affixed to the catheter and spaced away from the blood property change port to provide a signal corresponding to a change in blood property external to the catheter; the sensor is located in the catheter to minimize wall effects; a controller connected to the sensor to calculate the flow rate corresponding to the signal from the downstream sensor; the port includes an aperture for introducing a blood property variant; the blood property change port and the sensor are spaced apart by a sufficient distance to substantially mix an indicator into the blood; the port includes at least one of a heat sink and a heat source for creating a local temperature gradient; a dilution indicator port; the change in blood property includes one of a bolus injection and a constant infusion; the blood altering section includes one of a port and a temperature gradient generator; the sensor detects changes in one of electrical impedance and electrical resistance; and the sensor detects a thermal property of the blood. See Column 3, lines 25-63; Column 4, lines 60-67; Column 5, lines 1-7 and 26-49; and Column 6, lines 35-44.

Quinn et al however fail to disclose the use of a specific formula for the controller or processor to calculate the flow rate after the bolus is injected; the use of multiple catheters; the stenosis reducing procedure includes angioplasty.

Vogel et al disclose a steerable guidewire having electrodes for measuring vessel characteristics and blood flow and further disclose using a specific formula for the controller or processor to calculate the flow rate after the bolus is injected; the use of multiple catheters; the stenosis reducing procedure includes angioplasty. See Column 8, lines 24-66; and Column 9, lines 5-48.

Since both Quinn et al and Vogel et al disclose means for measuring the flow rate within a blood vessel by a dilution technique, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the and method of Quinn et al to include the use of a specific blood flow formula, the use of multiple catheters and reducing a stenosis using the balloon, as per the teachings of Vogel et al, since it would provide a means to measure the pre- and post-angioplasty flow rates to determine if further balloon inflations are necessary to reduce the blockage. It also would have been obvious to one of ordinary skill in the art to use the balloon of Quinn et al for an angioplasty procedure, since any balloon on the end of a catheter would be capable of inflation to reduce the stenosed region. It also would have been obvious to have the processor of Quinn et al to use the formula disclosed in Vogel et al to calculate the post-bolus injection flow rate, since it is well known in the art to use that formula to determine the blood flow in regular dilution or thermodilution techniques. Furthermore, it would have been obvious to one of ordinary skill in the art to conduct a pre- and post-angioplasty flow rate and perform the procedure again if the flow rate is still not sufficient. It also would have been obvious to rotate the sensor to reduce the wall effects in the vessel since it is well known in the art catheters have the ability to be

Art Unit: 3736

rotated while in the blood vessel. It also would have been obvious to provide multiple sensors on the catheter since it would provide a way to monitor a wide range of blood parameters, including oxygenation, glucose levels, flow rate, and cholesterol levels.

Response to Arguments

5. Applicant's arguments with respect to claims 2-6, 9-19 and 22-42 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj who's telephone number is (703) 308-3737 and group fax number is (703) 308-0758. The examiner can normally be reached on Monday-Friday, with second Fridays off.

BS

January 4, 2003



**MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700**